PSJ3

Exhibit 457

From: Zimmerman, Chris
Sent: Tue, 18 Mar 2014 18:12:01 -0400 (EDT)
To: Mays, Steve[SMays@amerisourcebergen.com]
Subject: RE: RAC Agenda for Thursday, March 20th at 3:00 PM (ET)

I guess a lot depends on where the other groups are: NACDS, NCPA, etc.

It may not be good for us if HDMA (distributors) are the only ones challenging DEA.

Also, feel out where the other members are. I think we need to be careful not to overplay our hand. On the other hand, if HDMA pushes, it could backfire and DEA could implement ASAP, no exceptions.

I would go into the call testing the water with where the other groups are. The more united the better, and I don't think HDMA wants to take on DEA alone, but it will be interesting to see where the other members shake out.

Chris

From: Mays, Steve
Sent: Tuesday, March 18, 2014 5:44 PM
To: Zimmerman, Chris
Subject: FW: RAC Agenda for Thursday, March 20th at 3:00 PM (ET)

Let me know your thoughts about the two issues below.

Steve Mays
Senior Director, Corporate Security & Regulatory Affairs
AmerisourceBergen
610.727.7467 Phone
102-7467 ABC Global Extension
321.278.3292 Cell
smays@amerisourcebergen.com

From: Tuszynski, Allison [mailto:atuszynski@hdmanet.org]
Sent: Tuesday, March 18, 2014 5:28 PM
To: Tuszynski, Allison
Subject: RAC Agenda for Thursday, March 20th at 3:00 PM (ET)

To: **HDMA Regulatory Affairs Committee**
Cc: **HDMA Legal Committee**

Re: **RAC Agenda for Thursday, March 20th at 3:00 PM (ET)**

Please do not share this email outside of your company.

Call-in Information:
Dial-in Number: 888-206-2266

Guest ID: 2533738

On this week's RAC call we will focus only on the hydrocodone-combination products proposed rule from DEA.

A list of points HDMA could provide in comments are at the end of this e-mail, including some thoughts on additional advocacy, followed by the preferences we've discussed for how DEA should treat HCP storage requirements. HDMA has already started drafting comments. However, two options need your input before we proceed much further on them since we have not raised them with DEA before:

Item #3 -- Should HDMA request a hearing, noted in the FR on p 11038 col. 3, which states "…this action is a formal rulemaking 'on the record after opportunity for a hearing?'" Such a hearing may benefit HDMA members by slowing the rulemaking, but is different from an FDA public meeting with panels of stakeholders describing their views. A hearing on this rule would be before an Administrative Law Judge. (David Durkin -- HDMA Outside Counsel from OFW -- will describe this type of hearing further on the call.) **Hearing requests must be submitted by March 28.**

Item #8 -- Should we comment to DEA that applying vault storage requirements, specified in 1301.72(a) *finalized in 1971*, may violate federal procedures for rulemaking? HDMA will explain how we might comment that automatic application does not allow adequate opportunity for public "notice and comment" as required of Federal Agency rulemakings.

For HDMA distributor members only
Draft Potential comment/advocacy options for DEA proposed hydrocodone regulation

Assuming that what we want DEA to do is, in priority order, as listed at the end of this e-mail, here are the possible comment/advocacy options we seek (generally in order of least aggressive to most aggressive.)

1. Comment that there is no cage/vault/warehouse security issue. Cost and disruption with no defined benefit. The newly enacted DQSA/DSCSA will deter diversion.

2. Ask DEA to simplify CSOS requirements (Note: changing CSOS would have to be a separate rulemaking. Alternatively, we could submit this as a petition after the final rule.)

3. **Request a hearing (p 11038) col 2 (Note: must be submitted by March 28)**

4. Comment that DEA's economic analysis is underestimated.

5. Comment that DEA hasn't followed Paperwork Reduction Act Requirements.

6. Meet with the Small Business Administration to voice concerns.

7. Comment that the final 1971 rule directing that Schedule II products be placed in vaults also indicated that the agency intended to use flexibility in how they applied this requirement.

8. **Comment that automatically subjecting HCPs to vault storage violates rulemaking procedures (Administrative Procedures Act --APA) because the vault placement rule is 40+ years old. No one could have commented adequately in 1971 on the impact of placing HCPs into vaults in 2014.**

9. Other (discuss additional options and comment submission strategies).

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Potential Hydrocodone Combination Product Storage Solutions

1. Exemption for all Hydrocodone combo products from the vault storage requirement.

2. Allow "Grandfathering." Products stored in warehouses built before the final upscheduling rule could remain in cages. Only products stored in warehouses built after the final rule date would have to be placed in vaults.

3. Exemption from the vault storage requirement, but require some further security features for cages storing hydrocodone combination products. Examples may include
   - Special/extra detection devices
   - Extra cameras
   - Other?

Note: Security features should be well defined and likewise subject to notice and comment as part of the proposed rule.

4. Allow "Grandfathering" as in #2 above, but the cages/warehouses eligible for grandfathering would be equipped with the same additional security features as for the exemption in #3 above.

5. Provide a long time frame, at least 5+ years, to build/expand vaults and move products into them.

Would members be willing to consider another concept we didn't discuss on 11/21 (only if DEA would not accept any of the above)? Specifically:

If DEA insists on placing these products in vaults in a short time frame, allow distributors to apply for a time extension through a well-defined request process. It would include conditions for both distributors and DEA. The process and conditions might include such features as:
- The distributor would provide documentation of the reasons for requesting additional time.
- The distributor's extension request must be for a defined period of time (e.g., a set number of years beyond the final rule date.)
- DEA must respond to an extension request within a defined period of time (e.g., 2 months?).
- Other?

We look forward to speaking with you on **Thursday, March 20th at 3:00 PM (ET).** In addition, we'd like to make you aware that we will still have our regular RAC call next week on Thursday, March 28th at 3:00 PM (ET). (The other RAC call this month was cancelled due to DMC.)

Please contact me if you have any questions.

Allison

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Allison Tuszynski
Regulatory Affairs Analyst
Healthcare Distribution Management Association
(703) 885-0266
www.HealthcareDistribution.org